Long term functional and morphological outcomes and patient satisfaction after cataract surgery with BiFlex M implantation with / without posterior central circular capsulorhexis (PCCC)

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Patient’s motivation for going to multifocal

• Demand for
  – quality vision restoration
  – presbyopic vision correction

• Active lifestyle
Vide variety of solutions

- Multifocal contact lenses
- Accomodative lenses
- Monovision correction
- Multifocal add-on IOL
- Multifocal IOL
  - Refractive
  - Diffractive
  - New technologies
Surgeons point of view

• **Patient satisfaction**
• Technical feasibility
• Lens performance
  – Multifocality
  – Artefacts – low level
  – Stability in refraction
• Prestige
• Financial safety
Patient eligibility

• Pathological status
  – Dry eye
  – Corneal scars
  – Macula affected
  – Unstable capsule

• Pupil diameter < 2,5 mm

• *Monofocal lens in the other eye*

• Postop. astigmatia < 0,75 D (direct)

• Perfectionist

• Cannot afford
Personal motivation

• Dealing with premium IOL and demanding patients needs:
  – Self confidence in refractive- and operation area
  – Technical and financial investment for long run
  – Time

• The BiFlex Multifocal IOL had excellent background
  – Powerful research- and engineer staff
    • Several patents
  – State of the art production technology

• Lucky enough to convince Medicontur of a prospective study
Personal motivation

• Dealing with premium IOL and demanding patients needs:
  – Self confidence in refractive- and operation area
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  – Time
• The BiFlex Multifocal IOL had excellent references
  – Extremely powerful research and engineer staff
  – State of the art production technology
• Lucky enough to convince Medicontur of a prospective study
• To find the right lens for my patients
Medicontur Bi-Flex M – Optical part

„Apodisation“

- Greek origin: “making legless”
- Steps taper towards PCL periphery
- PCL properties change radially towards periphery

Apodised diffractive part

- Better picture quality
- Light scatter artefacts decrease

Rods: 15 micron
Cones: 50-55 micron
SPHERICAL ABERRATION ON THE REFRACTIVE PART OF THE DIFFRACTIVE STEPS INCREASES THE DEPTH OF THE FOCUS

PROGRESSIVE VISION IN THE WHOLE ACCOMODATION RANGE

PAD = Progressive apodisation
IOL-material - High Abbe number (58)

• **Abbe number:**
  • Characterises the scatter of different wavelengths

• The higher is Abbe number, the less is chromatic aberration
Simulation of vision without and with yellow filter

IOL
With NO
Yellow filter

MEDICONTUR
Natural
Yellow filter

IOL
With NON natural
Yellow filter
Design and technical finish – optical edge

- „Sharp edge”
- 360 degree
- Curvature under 10 microns

10 micron | 35 micron | 60 micron | 25 micron
Design and technical finish – haptic design

- **Haptic:**
  - Re-formation after injection
  - Optimal centration
  - Stable position—that lasts

**Contact angle:** 88,8°
(Medicontur Bi-Flex) nearly 180 fok

67,7°
63,5°
Prospective study - objective

– **Patient selection** (up to 50)
– **Follow up until end of year 2**
  
  Preop.; op.; postop.
  
  Day 1; week 1; week 5;
  
  month 3; month 6;
  
  year 1; year 2

– **Objective conditions**
  
  • Cataract - otherwise healthy eyes

– **Subjective conditions**
  
  • Understanding of the study and willingness of multifocal function
  
  • Cooperation in examinations and follow ups
Prospective study

— Functionality

• Visual acuity
  Uncorrected/corrected
    » Distance
    » Intermediaer
    » Near
    — Defocus

• Contrast sensitivity
  — Mezopic
  — Photopic
  — Backlight

• Visual artefacts

• Straylight sensitivity
  — (at 1 & 2 years)

— Tools

• Certified examiners
  — ETDRS chart
  — Radner reading chart

• CSV-1000

• VFQ-25
• C-Quant
Prospective study

- Morphology
  - Position of the PC-IOL
    - Displacement
    - Rotation
    - Distorsion
    (Refraction stability)
  - Capsule
    - opacification
    - shrinkage
    - PCO development
  - IOL-surface
    - Displacement
    - Rotation
    - Distorsion
    (Refraction stability)
  - Macular changes

- Tools
  - Slitlamp, Applanation tonometry
  - Biomicroscopy
  - Refraction and keratometry
  - PC-IOL photography
    - small- and dilated pupil
  - OCT Spectralis
    - RNFL and macula
Operation and care

• Standard Phaco-technique
  – One eye with PCCC (posterior central circular capsulorhexis)
  – Fellow eye without PCCC
  – LRI if needed (1,25 D direct and 1,0 D indirect astigmia allowed)
  – Anterior capsule polishing
  – Uneventful operations

• Postoperation care:
  – Topical antibiotic (Vigamox) – 5 days 3x/day
  – Steroid (Maxidex)-1 month 4x/day tapered to 1x/day
  – NSAID (Nevanac) – 3x/day for 6 weeks
  – (Lubricant - if needed)
Multifocal PCL, mild PCO
Multifocal PCL, moderate PCO
Multifocal PCL, with capsulotomy
Monocular (uncorrected)
DISTANT VA (5m; *Decimal*)

Mean values:
All (91 eyes): 1,00;  PCCC (46 eyes): 1,032;  n/PCCC (45 eyes): 0,978  
min.: 0,5; max.: 1,6
Monocular (uncorrected) 
DISTANT VA (5m; LogMar)

Mean values:
All (91 eyes): 0.000; PCCC (46 eyes): -0.013; n/PCCC (45 eyes): 0.009
min.: 0.3; max.: -0.2
Need for correction

DISTANT (5m)

Refractive predictability;
Difference in targeted vs. achieved MRSE:

2 years / 91 eyes

D
Monocular uncorrected
INTERMEDIATE VA (60cm *Decimal*)

Mean values:
All (91 eyes): 0.88;  PCCC (46 eyes): 0.87;  n/PCCC (45 eyes): 0.89  min.: 0.5; max.: 1.6
Monocular uncorrected
INTERMEDIATE VA (60cm LogMar)

Mean values:
All (91 eyes): 0,06;  PCCC (46 eyes): 0,06;  n/PCCC (45 eyes): 0,05  min.: 0,3; max.: -0,1
Need for correction
INTERMEDIATE (60 cm)

Refractive predictability;
Difference in targeted vs. achieved MRSE:
Monocular uncorrected
NEAR VA (40cm *Decimal*)

Mean values:
All (91 eyes): 0.74;    PCCC (46 eyes): 0.74;    n/PCCC (45 eyes): 0.75    min.: 0.45; max.: 1.0
Monocular uncorrected NEAR VA (40cm LogMar)

Mean values:
All (91 eyes): 0.13; PCCC (46 eyes): 0.13; n/PCCC (45 eyes): 0.12  min.: 0.4; max.: 0.0
Need for correction
NEAR (40 cm)

Refractive predictability;
Difference in targeted vs. achieved MRSE:

2 years / 91 eyes
Defocus

With PCCC

No PCCC

Both eyes (simultaneously)
Compare to others
Bi-Flex M contra FineVision (Physiol) clear trifocal clinical performance of Bi-Flex M
Contrast-sensitivity
(2 years)
Contrast-sensitivity (2 years)
Contrast-sensitivity Mezopic — with time

3 months ➔ 6 months ➔ 1 year ➔ 2 years

No PCCC
PCCC
Contrast Sensitivity:

Comparison of Bi-Flex 677MY and FineVision

Photopic conditions

Mesopic conditions

Scotopic conditions

Bi-Flex 677 MY (AVG)
PhysIOL FineVision (AVG)
Straylight?
Straylight?

With PCCC

No PCCC
Need for wearing glasses

• Before operation (50 pat’s):
  – Distant:.........27
  – Intermedier:..39
  – Near:...............47

• 3 months:
  – Distant:.........0
  – Intermedier:..0
  – Near:...............0

• 24 months:
  – Distant:.........0
  – Intermedier:..0
  – Near:...............0
  – (One patient is wearing astigmia correction only)
<table>
<thead>
<tr>
<th>Visual Functioning Questionnaire (VFQ)</th>
<th>No problem</th>
<th>Mild</th>
<th>Moderate</th>
<th>Strong</th>
<th>Bad</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>50 patients / Score</strong></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

How much difficulty do you have with each of the following
Please tick the number from 1 to 6

- **Glare/Flare**
  (trouble seeing street signs due to bright light or oncoming headlight?)
  - 27
  - 20
  - 2
  - 1
  - 
  - 

- **Night vision**
  - 49
  - 1
  - 
  - 
  - 
  - 

- **Colour perception**
  (trouble recognizing specific colours)
  - 50
  - 
  - 
  - 
  - 
  - 

- **Halos**
  (rings around lights)
  - 20
  - 28
  - 1
  - 1
  - 
  - 

- **Depth perception**
  (trouble lining things up, pouring liquids or going down stairs)
  - 50
  - 
  - 
  - 
  - 
  - 

- **Distorted near vision**
  (straight lines looked crooked close up)
  - 50
  - 
  - 
  - 
  - 
  - 

- **Distorted distance vision**
  (straight lines looked crooked at distance)
  - 50
  - 
  - 
  - 
  - 
  - 

- **Blurred near vision**
  - 49
  - 1
  - 
  - 
  - 
  - 

- **Blurred far vision**
  - 50
  - 
  - 
  - 
  - 
  - 

- **Double vision**
  - 49
  - 1/?
  - 
  - 
  - 
  -
<table>
<thead>
<tr>
<th>Visual Functioning Questionnaire (VFQ)</th>
<th>Response 1 to 6-point scale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>VISUAL LIFESTYLE ACTIVITIES</strong></td>
<td>score</td>
</tr>
<tr>
<td>How much difficulty do you have with each activity due to your vision (without glasses or contact lenses)</td>
<td></td>
</tr>
<tr>
<td>Watching TV or movies</td>
<td>48 2 - - - - -</td>
</tr>
<tr>
<td>Playing or working outside</td>
<td>50 - - - - -</td>
</tr>
<tr>
<td>Caring for/playing with children</td>
<td>50 - - - - -</td>
</tr>
<tr>
<td>Reading the time on at alarm clock</td>
<td>48 2 - - - -</td>
</tr>
<tr>
<td>Seeing clearly when you wake up</td>
<td>46 4 - - - -</td>
</tr>
<tr>
<td>Reading the time on at wall clock</td>
<td>50 - - - - -</td>
</tr>
<tr>
<td>Performing your job/hobbies</td>
<td>48 2 - - - -</td>
</tr>
<tr>
<td>Participating in sports/recreation</td>
<td>50 - - - - -</td>
</tr>
<tr>
<td>Participating in social events</td>
<td>50 - - - - -</td>
</tr>
<tr>
<td>Reading and near work activities</td>
<td>48 2 - - - -</td>
</tr>
<tr>
<td><strong>Driving at night</strong></td>
<td></td>
</tr>
<tr>
<td>Driving when it is raining</td>
<td>48 2 - - - -</td>
</tr>
<tr>
<td>Using a computer</td>
<td>46 2 2 - - -</td>
</tr>
<tr>
<td>Cooking</td>
<td>50 - - - - -</td>
</tr>
<tr>
<td>Shopping</td>
<td>50 - - - - -</td>
</tr>
<tr>
<td>Using a cell phone</td>
<td>48 2 - - - -</td>
</tr>
<tr>
<td>Shaving or putting on make up</td>
<td>48 2 - - - -</td>
</tr>
</tbody>
</table>

50 patients
How satisfied are you with your vision? (2 year F/U)

Scores: 10 = perfect; 9 = very good; 8 = good; ........ 1 = unacceptable
Morphological results

Position of the lens at 12 months

*Mayor influence in refraction and artefacts*

- **Displacement**
  - narrow pupil photos: **NO DISPLACEMENT** (97/97)
- **Rotation**
  - Dilated pupil photos: **NO ROTATION** (97/97)
- **Distorsion**
  - Dilated pupil photos: **NO DISTORSION** (97/97)
  - (Artefacts +Refractive errors)

- **Capsule** (49 eyes with PCCC; 43 eyes no PCCC)
  - Opacification – Not significant
  - Folds – disappeared in 3 months (ecx.: 3/43 pat’s)
  - Shrinkage – No PCL displacement
  - PCO development:
    - In 1 year: 0 / 43 YAG-CT
    - In 2 years: 9 / 48 eyes for YAG-CT
PCL stability

Undilated  Dilated
PCL stability with time

Postop. day 1  Postop. month 12
PCL stability with time

IOLs rotated $3.61 \pm 2.34$ degrees between postoperation day and 1 month; 0 degree thereafter.
Tips and tricks

• Patient selection – still challenging
• Best results: simultaneous operation
  – Neuroadaptation enhanced
• Biometry – crucial role
• Avoid fundus pathologies
  – (Diabetes, ARM!!!)
• Good surgery – focus to capsule cleaning!
• Postoperation care – NSAID use
Conclusion

• Nearly total glasses independence
• Good functional and excellent morphological results
  – Predictability and stability are very good
  – Visual artifacts were of low level and easy to tolerate; improving with time
• Works rather as multifocal – not bi- or trifocal
• PCCC did not have significant influence to visual functions and lens position
Thank you for your attention!